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Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	}	AT	ATTORNEY DOCKET NO.	
09/508,5	10 05/26	/00 TSCHOPE		M	P100564-0000	
			1	EXAMINER		
004372 ARENT FOX KINTNER PLOTKIN & KAHN			F	PRASAD,S		
1050 CONNECTICUT AVENUE, N.W.			ART U	NIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

<u>**</u>		Applicatio	n No.	Applicant(s)	4-4-a-**-				
	•	09/508,51	0	Tshope et al.					
	Office Action Summary	Examiner		Art Unit					
		Sarada C F	Prasad	1646					
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address								
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) FROM									
THE I - Exter after - If the - If NO - Failu - Any r eame	MAILING DATE OF THIS COMMUNICATIOns is signs of time may be available under the provisions of 37 CF six (6) MONTHS from the mailing date of this communication period for reply specified above is less than thirty (30) days, a period for reply is specified above, the maximum statutory pere to reply within the set or extended period for reply will, by seply received by the Office later than three months after the new digital patent term adjustment. See 37 CFR 1.704(b).	ON. R 1.136(a). In no event. In a reply within the statueriod will apply and will statute, cause the appli	nt, however, may a reply be tin tory minimum of thirty (30) day expire SIX (6) MONTHS from cation to become ABANDONE	nely filed s will be considered timely. the mailing date of this communi D (35 U.S.C. § 133).	cation.				
Status	5 ( ) 5 ( ) 5 ( )	040	2004	·					
1) 🖂	Responsive to communication(s) filed on								
2a)□	<i>,</i> —	This action is			-:4 :-				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.									
Dispositi	on of Claims				•				
	Claim(s) <u>1-26</u> is/are pending in the applica								
	4a) Of the above claim(s) is/are with	ndrawn from cor	nsideration.						
5) Claim(s) is/are allowed.									
6) Claim(s) is/are rejected.									
7)	Claim(s) is/are objected to.								
8) Claim(s) <u>1-26</u> are subject to restriction and/or election requirement.									
Applicati	on Papers								
9) The specification is objected to by the Examiner.									
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.									
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).									
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.									
If approved, corrected drawings are required in reply to this Office action.									
12) The oath or declaration is objected to by the Examiner.									
•	under 35 U.S.C. §§ 119 and 120			V ( IV = + (5)					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).									
a)	☐ All b)☐ Some * c)☐ None of:								
	1. Certified copies of the priority documents have been received.								
2. Certified copies of the priority documents have been received in Application No									
<ul> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>									
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).									
<ul> <li>a)  The translation of the foreign language provisional application has been received.</li> <li>15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>									
Attachment(s)									
1)  Notice  No	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-94) mation Disclosure Statement(s) (PTO-1449) Paper N			ry (PTO-413) Paper No(s) Patent Application (PTO-152					

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## **Detailed Action**

This application is a 371 of PCT/EP98/06065. For applications filed under 371, PCT Rules for lack of unity apply.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept. Under PCT Rule 13.1 the following combinations of claims of different categories are permissible and restriction to one of the following combinations is required.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

The Groups are as follows:

Group I: Claims 1-15, 18-26, drawn to liquid formulation comprising human interferon- $\beta$  of improved shelf life.

Group II: Claims 16, 17 drawn to liquid formulation comprising human interferon- $\beta$  with additional methionine, of improved shelf life.

Groups I-II are drawn to distinct polypeptides which do not share the same or a corresponding special technical feature which define the contribution of each invention. The products of Groups I and II do not share a corresponding special technical feature, because the product comprising formulations of a polypeptide of interferon-β as in Group I is different from the product comprising formulations of a polypeptide of interferon-β containing methionine as in Group II. The peptides of Group I and Group II can be used for entirely different purposes and can be generated by entirely different process steps. Therefore each of the inventions with patentably distinct uses are not related and hence a search for one would not reveal art for

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another. Since these special technical features are not shared by each process, and since the common features do not establish an advance over the prior art, the inventions of Groups I-II do not form a single inventive concept within the meaning of Rule 13.2.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday - Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D. Examiner Art Unit 1646 September, 28th, 2001

> YVONNE EYLER, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600